

**TRANSMITTAL  
FORM**

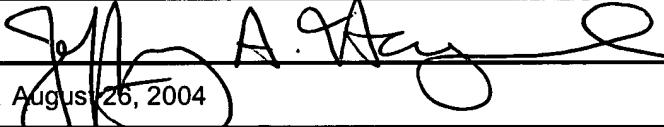
(to be used for all correspondence after initial filing)

		Application Number	09/846,893
		Filing Date	May 1, 2001
		First Named Inventor	J. Kevin Judice et al.
		Art Unit	1653
		Examiner Name	Samuel W. Liu
Total Number of Pages in This Submission	14	Attorney Docket Number	P-105-US1

**ENCLOSURES (check all that apply)**

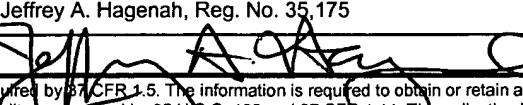
<input checked="" type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment / Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Response to Missing Parts/ Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input checked="" type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____	<input type="checkbox"/> After Allowance Communication to Technology Center (TC) <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): <b>Return Postcard</b>
<div style="display: flex; justify-content: space-around;"> <div style="border: 1px solid black; padding: 2px;">Remarks</div> <div>Enclosed are the following:</div> </div> <p>Petition for Reconsideration of Patent Term Adjustment (3 pages) including copy of Notice of Allowance (8 pages); Fee Transmittal (1 page in duplicate); and this transmittal form (1 page). Total = 14 pages + return postcard</p>		

**SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT**

Firm or Individual name	Jeffrey A. Hagenah, Reg. No. 35,175	
Signature		
Date	August 26, 2004	

**CERTIFICATE OF EXPRESS MAILING**

I hereby certify that these papers or fee are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. §1.10 on the date indicated below and are addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450. Express Mail Label No.: EV 399287883 US

Typed or printed name	Jeffrey A. Hagenah, Reg. No. 35,175		
Signature		Date	August 26, 2004

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.



# FEE TRANSMITTAL for FY 2004

Effective 10/01/2003. Patent fees are subject to annual revision.

Applicant claims small entity status. See 37 CFR 1.27

**TOTAL AMOUNT OF PAYMENT** (\$ 200)

Complete if Known	
Application Number	09/846,893
Filing Date	May 1, 2001
First Named Inventor	J. Kevin Justice
Examiner Name	Samuel W. Liu
Art Unit	1653
Attorney Docket No.	P-105-US1

## METHOD OF PAYMENT (check all that apply)

Check  Credit card  Money  Other  None  
Order

Deposit Account:

Deposit  
Account  
Number

50-0344

Deposit  
Account  
Name

Theravance, Inc.

The Director is authorized to: (check all that apply)

Charge fee(s) indicated below  Credit any overpayments  
 Charge any additional fee(s) during the pendency of this application  
 Charge fee(s) indicated below, except for the filing fee  
to the above-identified deposit account.

## FEE CALCULATION

### 1. BASIC FILING FEE

Large Entity	Small Entity	Fee Description	Fee Paid
Fee Code	Fee (\$)	Fee Code (\$)	
1001	770	2001	385
1002	340	2002	170
1003	530	2003	265
1004	770	2004	385
1005	160	2005	80
SUBTOTAL (1)		(\$ 0)	

### 2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

Total Claims	Independent Claims	Extra Claims	Fee from below	Fee Paid
		-0 **	= 0 X 18	= 0
		-3 **	= 0 X 86	= 0
			X 290	= 0

### Large Entity

Large Entity	Small Entity	Fee Description
Fee Code	Fee (\$)	Fee Description
1202	18	2202 9 Claims in excess of 20
1201	86	2201 43 Independent claims in excess of 3
1203	290	2203 145 Multiple dependent claim, if not paid
1204	86	2204 43 ** Reissue independent claims over original patent
1205	18	2205 9 ** Reissue claims in excess of 20 and over original patent
SUBTOTAL (2)		(\$ 0)

*\*\*or number previously paid, if greater; For Reissues, see above*

## 3. ADDITIONAL FEES

Large Entity	Small Entity	Fee Description	Fee Paid
Fee Code	Fee (\$)	Fee Code (\$)	
1051	130	2051 65 Surcharge - late filing fee or oath	
1052	50	2052 25 Surcharge - late provisional filing fee or cover sheet.	
1053	130	1053 130 Non-English specification	
1812	2,520	1812 2,520 For filing a request for reexamination	
1804	920*	1804 920* Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805 1,840* Requesting publication of SIR after Examiner action	
1251	110	2251 55 Extension for reply within first month	
1252	420	2252 210 Extension for reply within second month	
1253	950	2253 475 Extension for reply within third month	
1254	1,480	2254 740 Extension for reply within fourth month	
1255	2,010	2255 1,005 Extension for reply within fifth month	
1401	330	2401 165 Notice of Appeal	
1402	330	2402 165 Filing a brief in support of an appeal	
1403	290	2403 145 Request for oral hearing	
1451	1,510	1451 1,510 Petition to institute a public use proceeding	
1452	110	2452 55 Petition to revive – unavoidable	
1453	1,330	2453 665 Petition to revive – unintentional	
1501	1,330	2501 665 Utility issue fee (or reissue)	
1502	480	2502 240 Design issue fee	
1503	640	2503 320 Plant issue fee	
1460	130	1460 130 Petitions to the Commissioner	
1807	50	1807 50 Processing fee under 37 CFR 1.17 (q)	
1806	180	1806 180 Submission of Information Disclosure Stmt	
8021	40	8021 40 Recording each patent assignment per property (times number of properties)	
1809	770	2809 385 Filing a submission after final rejection (37 CFR § 1.129(a))	
1810	770	2810 385 For each additional invention to be examined (37 CFR § 1.129(b))	
1801	770	2801 385 Request for Continued Examination (RCE)	
1802	900	1802 900 Request for expedited examination of a design application	
Other fee (specify) <u>Filing an application for patent term adjustment</u>			200

\*Reduced by Basic Filing Fee Paid

**SUBTOTAL (3)**

(\$ 200)

## SUBMITTED BY

Name (Print/Type)	Jeffrey A. Hagenah	Registration No. (Attorney/Agent)	35,175	Telephone	(650) 808-6406	Complete (if applicable)
Signature				Date	August 26, 2004	

**WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.**

This collection of information is required by 37 CFR 1.17 and 1.27. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing this form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.



8/27/04

DAC  
EP  
IAW

Certificate of Express Mailing

Express Mail Label No.: EV 399287883 US

I hereby certify that this paper is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. §1.10 and is addressed to: Mail Stop Petition, Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450 on the date indicated below.

By: Barbara Bryant  
Barbara Bryant

Date: August 26, 2004

PATENT  
Attorney Docket No. P-105-US1

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of )  
J. Kevin Judice et al. ) Group Art Unit: 1653  
Application No.: 09/846,893 ) Examiner: Samuel W. Liu  
Filed: May 1, 2001 ) Confirmation No. 5900  
For: PHARMACEUTICAL COMPOSITIONS )  
CONTAINING A GLYCOPEPTIDE )  
ANTIBIOTIC AND A CYCLODEXTRIN )

**REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT  
INDICATED IN NOTICE OF ALLOWANCE (37 C.F.R. § 1.705)**

Mail Stop Petition  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Applicant respectfully requests reconsideration of the patent term adjustment indicated on the Notice of Allowance mailed on July 15, 2004, for the above-identified patent application. This paper is being filed on even date with payment of the issue fee.

1. Statement of Facts

Pursuant to 37 C.F.R. §1.705(b)(2), Applicants respectfully submit the following statement of the facts involved:

A. 37 C.F.R. § 1.705(b)(2)(i) and (ii)

The patent term adjustment shown on the Notice of Allowance is 422 days. Assuming that a patent issues on the Tuesday before the date that is 28 weeks after mailing of the Notice of Allowance, i.e., on January 25, 2005, Applicant respectfully submits that the patent is entitled to an additional 269 days of patent term adjustment under 37 C.F.R. § 1.702 (b). Accordingly, the correct patent term adjustment under §1.702 is 691 days (assuming the patent issues on January 25, 2005).

The basis on which Applicants seek adjustment is as follows:

(a) Period of Adjustment Pursuant to 37 C.F.R. §§1.702(a) and 1.703(a)

Pursuant to 37 C.F.R. § 1.702(a)(1), the USPTO failed to mail at least one of a notification under 35 U.S.C. §132 or a notice of allowance under 35 U.S.C. §151 not later than fourteen months after the date on which the application was filed under 35 U.S.C. §111(a). Specifically, the date of filing for this application is May 1, 2001; and the USPTO issued a first Office Action on August 27, 2003, resulting in 422 days of USPTO delay. This period of patent term adjustment is shown correctly on the Notice of Allowance.

(b) Period of Adjustment Pursuant to 37 C.F.R. §§1.702(b) and 1.703(b)

Pursuant to 37 C.F.R. § 1.702(b), if the USPTO fails to issue a patent within three years of the actual filing date of the application, Applicant will be entitled to an additional patent term adjustment beginning on the day after the date that is three years after the date on which the application was filed under 35 U.S.C. §111(a) and ending on the date a patent was issued. The Notice of Allowance indicates that a patent will issue on the Tuesday before the date that is 28 weeks after the mailing date of the Notice of Allowance, i.e., a patent will issue on January 25, 2005. A copy of Notice of Allowance for this application is attached hereto. Accordingly, if the patent issues as indicated in the Notice of Allowance, Applicant is entitled to 269 days of additional patent term adjustment. **The exact additional patent term adjustment will depend**

**on the actual issue date of the patent.** The USPTO has not shown any patent term adjustment based on 37 C.F.R. § 1.702(b) on the Notice of Allowance.

**B. 37 C.F.R. §1.705(b)(2)(iii)**

This patent application (and the patent issuing from this application) is not subject to a terminal disclaimer.

**C. 37 C.F.R. §1.705(b)(2)(iv)**

Applicants are not aware of any circumstances during the prosecution of this application that constitute a failure to engage in reasonable efforts to conclude processing or examination of this application as set forth in 37 C.F.R. §1.704.

**D. Summary**

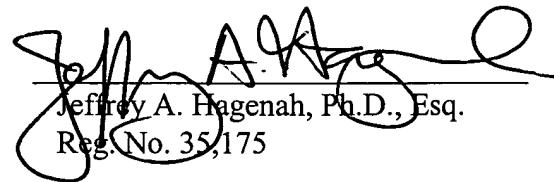
Applicants respectfully request the patent issuing from the above-identified patent application be granted, in addition to the 422 days under 37 C.F.R. § 1.702(a)(1), the appropriate patented term adjustment under 37 C.F.R. § 1.702(b) based on the actual issue date of the patent.

**2. Fee Pursuant to 37 C.F.R. §1.18(e)**

Pursuant to 37 C.F.R. §1.705(b)(1), a Fee Transmittal is enclosed authorizing the Commissioner to charge the Petition fee of \$200.00 set forth in 37 C.F.R. § 1.18(e) to deposit account 50-0344. The Commissioner is also authorized to charge any additional fees or credit any overpayment to this deposit account. The Fee Transmittal is submitted in duplicate.

Should there be any questions concerning this paper, please contact the undersigned attorney at (650) 808-6406.

Respectfully submitted,

  
Jeffrey A. Hagenah, Ph.D., Esq.  
Reg. No. 35,175

Date: August 26, 2004

THERAVANCE, INC.  
901 Gateway Boulevard  
South San Francisco, CA 94080  
Tel: (650) 808-6000 Fax: (650) 808-6078



UNITED STATES PATENT AND TRADEMARK OFFICE



UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

27038

THERAVANCE, INC.  
901 GATEWAY BOULEVARD  
SOUTH SAN FRANCISCO, CA 94080

07/15/2004

RECEIVED		EXAMINER
		LIU, SAMUEL W
JUL 20 2004		ART UNIT
		PAPER NUMBER
THERAVANCE, INC. LEGAL DEPARTMENT		1653
DATE MAILED: 07/15/2004		

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/846,893	05/01/2001	J. Kevin Judice	P-105-R	5900

TITLE OF INVENTION: PHARMACEUTICAL COMPOSITIONS CONTAINING A GLYCOPEPTIDE ANTIBIOTIC AND A CYCLODEXTRIN

APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1330	\$300	\$1630	10/15/2004

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE REFLECTS A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE APPLIED IN THIS APPLICATION. THE PTOL-85B (OR AN EQUIVALENT) MUST BE RETURNED WITHIN THIS PERIOD EVEN IF NO FEE IS DUE OR THE APPLICATION WILL BE REGARDED AS ABANDONED.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL should be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). Even if the fee(s) have already been paid, Part B - Fee(s) Transmittal should be completed and returned. If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

**IMPORTANT REMINDER:** Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

*Issue Fee & Publication  
Fee due 10/15/04*

## PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail

**Mail Stop ISSUE FEE**  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
**or Fax (703) 746-4000**

**INSTRUCTIONS:** This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

27038 7590 07/15/2004

**THERAVANCE, INC.**  
901 GATEWAY BOULEVARD  
SOUTH SAN FRANCISCO, CA 94080



Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

### Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (703) 746-4000, on the date indicated below.

(Depositor's name)

(Signature)

(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/846,893	05/01/2001	J. Kevin Judice	P-105-R	5900

**TITLE OF INVENTION: PHARMACEUTICAL COMPOSITIONS CONTAINING A GLYCOPEPTIDE ANTIBIOTIC AND A CYCLODEXTRIN**

APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
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nonprovisional	NO	\$1330	\$300	\$1630	10/15/2004
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EXAMINER	ART UNIT	CLASS-SUBCLAS
LIU, SAMUEL W	1653	514-008000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).	2. For printing on the patent front page, list (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.
<input type="checkbox"/> Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.	1 _____

"Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required.

**3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)**

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent);  individual  corporation or other private group entity  government

4a. The following fee(s) are enclosed:	4b. Payment of Fee(s):
<input type="checkbox"/> Issue Fee	<input type="checkbox"/> A check in the amount of the fee(s) is enclosed.
<input type="checkbox"/> Publication Fee (No small entity discount permitted)	<input type="checkbox"/> Payment by credit card. Form PTO-2038 is attached.
<input type="checkbox"/> Advance Order - # of Copies _____	<input type="checkbox"/> The Director is hereby authorized by charge the required fee(s), or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

**5. Change in Entity Status (from status indicated above)**

a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27.  b. Applicant is not claiming SMALL ENTITY status. See, e.g., 37 CFR 1.27(g)(2).

The Director of the USPTO is requested to apply the Issue Fee and Publication Fee (if any) or to re-apply any previously paid issue fee to the application identified above.

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

(Authorized Signature)

(Date)

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

TRANSMIT THIS FORM WITH FEE(S)



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/846,893	05/01/2001	J. Kevin Judice	P-105-R	5900
27038	7590	07/15/2004	EXAMINER	
THERAVANCE, INC. 901 GATEWAY BOULEVARD SOUTH SAN FRANCISCO, CA 94080			LIU, SAMUEL W	
			ART UNIT	PAPER NUMBER
			1653	
DATE MAILED: 07/15/2004				

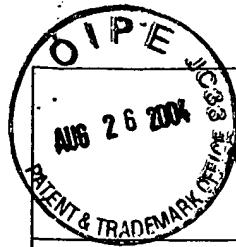
## Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 422 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 422 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (703) 305-1383. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at (703) 305-8283.



## Notice of Allowability

Notice of Allowability	Application No.	Applicant(s)
	09/846,893	JUDICE ET AL.
	Examiner Samuel W Liu	Art Unit 1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1.  This communication is responsive to 12-10-03 and 5-15-03.
2.  The allowed claim(s) is/are 1-10.
3.  The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
4.  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All    b)  Some\*    c)  None    of the:
  1.  Certified copies of the priority documents have been received.
  2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3.  Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

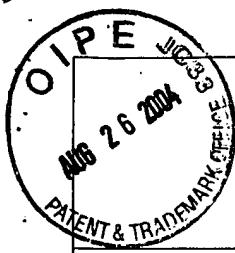
\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5.  A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6.  CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.  
(a)  including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached  
1)  hereto or 2)  to Paper No./Mail Date \_\_\_\_\_.  
(b)  including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
7.  DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

### Attachment(s)

1.  Notice of References Cited (PTO-892)
2.  Notice of Draftsperson's Patent Drawing Review (PTO-948)
3.  Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4.  Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5.  Notice of Informal Patent Application (PTO-152)
6.  Interview Summary (PTO-413),  
Paper No./Mail Date 6-28-04.
7.  Examiner's Amendment/Comment
8.  Examiner's Statement of Reasons for Allowance
9.  Other \_\_\_\_\_.



## ***Interview Summary***

<b>Application No.</b>	<b>Applicant(s)</b>
09/846,893	JUDICE ET AL.
<b>Examiner</b>	<b>Art Unit</b>
Samuel W Liu	1653

All participants (applicant, applicant's representative, PTO personnel):

(1) Samuel W Liu.

(3)

(2) Jeffrey A. Hagenah.

(4) .

Date of Interview: 28 June 2004.

Type: a) Telephonic b) Video Conference  
c) Personal [copy given to: 1) applicant 2) applicant's representative]

Exhibit shown or demonstration conducted: d)  Yes e)  No.  
If Yes, brief description: \_\_\_\_\_

Claim(s) discussed: 6 and 14-17.

### Identification of prior art discussed:

Agreement with respect to the claims f)  was reached. g)  was not reached. h)  N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Applicants agree the Examiner proposed amendment to claim 6, and agree to cancel claims 14-17 without prejudice.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

*Karen Carlson*  
KAREN COCHRANE CARLSON, PH.D  
PRIMARY EXAMINER

**Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.**

**Examiner's signature, if required**

## Summary of Record of Interview Requirements

### Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

### Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

#### 37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,  
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

### Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.



## DETAILED ACTION

The terminal disclaimer filed on 10 December 2003 disclaiming the terminal portion of any patent granted on this application, which would extend beyond the expiration date of US Application Nos. 09/776486 has been reviewed and are accepted. It of note that applicants previously canceled claims 11-13 and 18-19 (see the applicants' amendment filed 15 May 2003).

The pending claims 1-10 and 14-17 are therefore examined in this Office action.

## EXAMINER'S AMENDMENT

An Examiner's Amendment to the record appears below. Should the change and/or additions be unacceptable to Applicant, an amendment may be filed as provided by 37 C.F.R. § 1.312. To ensure consideration of such an amendment, it MUST be submitted no latter than payment of the Issue Fee.

Authorization for this Examiner's Amendment was given in a telephone interview with Jeffrey A. Hagenah 28 June 2004. Applicants agree the Examiner proposed amendment to claim 6, and agree to cancel claims 14-17 without prejudice (see below).

### **Amendments to the claim:**

The pending claims 6 and 14-17 have been amended or canceled as follows. Please replace the previous claims with the claim shown below.

**Claim 6 (Amended):** Change "provided that the components of the composition total 100 weight percent" to "based on 100 weight percent of the composition".

Claims 14-17 are deleted.

### **Amendments to the specification:**

At page 29, lines 20-23, change "U.S. Patent Nos. 5,840,684, 5,843,889, 5,916,873, 5,919,756, 5,952,310, 5,977,062, 5,977,063, EP 667, 353, WO 98/52589, WO99/56760, WO 00/04044, WO 00/39156" to "U.S. Patent Nos: 5,840,684, 5,843,889, 5,916,873, 5,919,756,

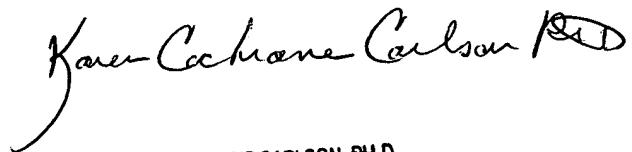
Art Unit: 1653

5,952,310, 5,977,062, 5,977,063, and foreign patents: EP 667, 353, WO 98/52589, WO99/56760, WO 00/04044, WO 00/39156".

*Conclusion:* Claims 1-10 are allowable over the art of record.

Any comments considered necessary by applicants must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Samuel Wei Liu, Ph.D. whose telephone number is (571) 272-0949. The Examiner can normally be reached daily except alternate Fridays from 8:30 A.M. to 5:30 P.M. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christopher Low, can be reached at (571) 272-0951. The official fax number for Technology Center 1600 is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.



KAREN COCHRANE CARLSON, PH.D.  
PRIMARY EXAMINER



Samuel W. Liu, Ph.D.

Art Unit 1653, Examiner

June 28, 2004